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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,978	12/16/1999	NING ZHANG	PXE-012.US	9639
23419	7590	10/23/2003	EXAMINER	
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	23

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,978

Applicant(s)

ZHANG ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/16/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response filed 9-10-02 and 1-30-03 have been received and entered. The inadvertent error in sending a non-responsive letter in response to the applicants' response of 9-10-02 is regretted.

Drawings

The specification is objected to because it does not describe all the drawings. For example, figures 3 contains 3C-1 to 3C-2, figure 4 contains 4B-1 to 4B-4 and 15 contains 15-1 to 15-4, however the specification does not provide description of these figures. Appropriate correction is required. Additionally, drawings are objected to as described in the PTO 948.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office of 3-13-02.

Response to Arguments

Applicant's arguments filed 9-10-02 have been fully considered but they are not persuasive. Applicants have argued that phenotype of the transgenic animals of the claimed invention is the ability to express a light generating protein, wherein expression of the light-generating protein is regulated by VEGFR-2 derived transcriptional regulator, however these arguments are not persuasive because

ability to express is not a phenotype, rather the expression of the reporter gene is a phenotype and the claims do not recite this. It is noted that due to the unpredictability of transgenic technology, comprising an expression cassette comprising a construct does not predict that the gene comprised in the construct will be expressed. Applicants further argue that the claimed invention is not to a gene knock-out mice and that a phenotype is created by introducing a reporter gene into the transgenic animals. As stated earlier "ability to express" is not a phenotype and the claims do not recite a phenotype.

It is noted that the recitation of the phenotype in the claim will obviate the rejection.

4. Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse or progeny thereof whose genome comprises an expression cassette comprising a cis-acting transcription regulator operably linked to a reporter sequence encoding a light-generating protein, wherein said cis-acting sequence consists of the sequence disclosed in SEQ ID NO:35, which comprises the sequence of SEQ ID NO:32 and wherein said light generating protein is expressed during angiogenesis, does not reasonably provide enablement for other embodiments, for reasons of record set forth in the previous office action of 3-13-02. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

It is noted that in view of applicants' amendments that SEQ ID NO 32 comprises the sequence of SEQ ID NO:35 (the VEGFR-2 enhancer sequence) and the 132 declaration of Dr. Zhang submitted in the response of 2-4-02, the full lack of enablement has been modified to scope of rejection. It is further noted that in view of the modified rejection some of the Applicant's arguments are moot as pertinent to full lack of enablement. However, applicants' arguments are not

sufficient to address the scope of enablement rejection. It is noted that for an artisan to be able to use the claimed transgenic mouse, it has to express the reporter protein, which will be expressed when the VEGFR-2 promoter is expressed that is active during angiogenesis and in view of unpredictability of the art of transgenesis, one can not predict what will be phenotype of the transgenic unless the reporter gene is expressed in the mouse during angiogenesis. In fact, the 132 declaration shows that the transgenic mouse expresses the reporter gene during neonatal or early post natal development when the angiogenesis is occurring. In other words, any transgenic mouse comprising the expression cassette as recited would not express the reporter gene unless angiogenesis is occurring. Additionally, the claimed transgenic mouse is to be used for screening of compounds and for an artisan to use the claimed transgenic mouse for the intended use, the transgenic mouse has to express the reporter gene. Applicants have argued that the claimed invention is not to a method of screening but to a transgenic mouse, however, the intended use of the mouse is for screening and therefore, for the invention to be enabled, an artisan should be able to use for the intended utility and because expression of the reporter gene is dependent on angiogenesis, such a phenotype will be essential for the transgenic mouse to be used for the intended utility.

5. The double patenting rejection has been withdrawn in view of the applicants' arguments.

6. No claim is allowed.


7. It is noted that a transgenic mouse or progeny thereof whose genome comprises an expression cassette comprising a cis-acting transcription regulator operably linked to a reporter sequence encoding a light-generating protein, wherein said cis-acting sequence consists of the sequence disclosed in SEQ ID NO:35, which comprises the sequence of SEQ ID NO:32 and wherein said light generating protein is expressed during angiogenesis is free of the prior art of record.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.


RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632